DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 5, 2015

Acumed, LLC
Mr. Nathan Wolf
Regulatory Specialist
5885 North West Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K143276
Trade/Device Name: Acumed Small Bone IM Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 12, 2014
Received: November 14, 2014

Dear Mr. Wolf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143276

Device Name
Acumed Small Bone IM Nail System

Indications for Use *(Describe)*
The Acumed Small Bone IM Nail System is intended for fixation of fractures and osteotomies of the fibula, radius, and ulna, including fractures where the medullary canal is narrow or flexibility of the implant is paramount.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Contact Details

Applicant Name: Acumed LLC
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503-207-1502 (Desk)
503-520-9618 (Fax)

Date Prepared: 12 November 2014

Device Name

Trade Name: Acumed Small Bone IM Nail System

Common Name: Intramedullary Fixation Rod/Pin

Classification: 21 CFR 888.3020, Intramedullary Fixation Rod

Class: Class II

Product Code: HSB

Legally Marketed Predicate Device(s)

The Synthes Elastic Intramedullary Nail (EIN), cleared in 1997 (K971783), the Synthes EIN End Cap, cleared in 2008 (K082148), and the Acumed Small Bone Locking Rod System II, cleared in 2003 (K031438) serve as the predicate devices.

Device Description

The Acumed Small Bone IM Nail is a titanium alloy (Ti-6Al-4V) intramedullary rod/nail manufactured in multiple lengths (110mm to 270mm) and diameters (2.6mm to 4.0mm). The nails have openings used in conjunction with titanium alloy cortical screws, which lock them in place. The nails are compatible with an optional far-end locking (FEL) bushing and set screw that provide a locking option at the distal end of the nail. The nails are also compatible with optional end caps that thread into the proximal portion of the nail to provide additional length if desired. All implants are provided both sterile and non-sterile.

Acumed Small Bone IM Nail System
510(k) Notification

Intended Use/Indications for Use

The Acumed Small Bone IM Nail System is intended for fixation of fractures and osteotomies of the fibula, radius, and ulna, including fractures where the medullary canal is narrow or flexibility of the implant is paramount.

Substantial Equivalence Comparison

In consideration of the comparisons given herein, the Acumed Small Bone IM Nail System has been determined to be substantially equivalent to its predicate devices, the Synthes EIN (K971783), Synthes EIN End Cap (K082148), and Acumed Small Bone Locking Rod System II (K031438). Substantial equivalence was determined due to similarities in materials, technology, function, and dimensions.

Non-clinical Testing

Comparative testing between the Acumed Small Bone IM Nailing system and a predicate device was conducted as per ASTM F1264-03. The test data showed the Acumed Small Bone IM Nail was substantially equivalent to the predicate device in a static four-point bend test, static torsion test, and bending fatigue test as described herein.